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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,749	06/25/2001	Jordan L. Holtzman	11909.1USWO	2030

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/830,749	HOLTZMAN, JORDAN L.	
	Examin r	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE f this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *23 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/23/03 has been entered.

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

3. Applicant's arguments filed 10/23/03 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-3 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention, for the reasons made of record in Paper No: 9 (mailed 4/23/03), and as follows.

Applicants argue on pages 3-4 of the response that a "patent need not teach, and preferably omits, what is well known in the art", and therefore, "there is no need to include them in the specification", and cites *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* and *Union Oil Co. Of Cal. v. Atlantic Richfield Co.* However, as previously made of record and in contrast to Applicants' assertions, it is the specification on page 6 that defines the breadth of the current claims in that "[a]s used herein, Q2 refers to any of the common names for this protein, including TPDO-Q2, Erp57, and Grp58 ***and all naturally occurring variant forms of this protein***... [emphasis added]". In contrast, evidence of a single bovine, human, mouse and rat Q2 sequence in the art does not reasonably allow one of ordinary skill in the art to visualize what critical amino acids defines "all naturally occurring variant forms of this protein", as encompassed by the claims, especially when no definable structure and function are recited in the claims; thereby, not reasonably meeting the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons previously made of record.

Second, as previously made of record and in contrast to Applicants' assertions, page 5 of the specification states that "[k]nown features of amyloid precursor protein and β-amyloid include *mammalian* genes encoding them", and that "β-amyloid can be made and/or isolated in *a* ***variety of forms*** [emphasis added]". In contrast, evidence of a single human β-amyloid protein, even from multiple publications, does not reasonably allow one of ordinary skill in the art to visualize what critical amino acids defines the elected *genus* of "comprises **animal** β-amyloid 1-42", as claimed, especially when no definable structure nor function is recited in the claims,

especially as it relates to no description within the specification or claims of any different species of β-amyloid, or what constitutes any generic β-amyloid protein in the art; thereby, not reasonably meeting the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons previously made of record. See MPEP 2163.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), "an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. In contrast, no polypeptides species definable by SEQ ID NO have been described in the instant specification; especially as it relates to any naturally-occurring variants of Q2 or animal β-amyloid.

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is",

and that:

"A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218".

In contrast, an invitation for others to discover a representative number of species with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics has not reasonably been provided within the instant specification, or well known in the art. Thus, Applicants are not reasonably in possession of the genus of a Q2 and animal β-amyloid protein complex at the time of filing the instant application, as currently claimed.

6. Claims 1-3 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a structurally definable chaperone Q2 and β-amyloid polypeptide complex, does not reasonably provide enablement for any complex comprising biologically functional equivalent forms of Q2 or β-amyloid with no known or recited structural and functional characteristics. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 9 (mailed 4/23/03), and as follows.

Applicants argue on pages 4-5 of the response that "Applicants have amended claim 1 to recite a native Q2 and a native β-amyloid". However, in contrast to Applicants' argument that now "randomly mutated *non-native* Q2 or β-amyloid related polypeptides" are no longer claimed and therefore the claims are enabled, the issue remains that the claims still encompass "all *naturally* occurring *variant forms* of th[ese] protein[s]", which include randomly native mutated sequences, by definition. Therefore, consistent with the teachings of Rudinger previously made of record, because no structure and appropriate functional language is recited in the claims for

one of skill in the art to know how to make the claimed invention, it would require undue experimentation to determine such because of the lack of guidance provided in the instant specification, for the reasons previously made of record; thereby, not reasonably meet the enablement requirements under 35 U.S.C. 112, first paragraph. Therefore, Applicants' arguments are not persuasive, for the reasons previously made of record; especially as it relates to the putative biologically functional equivalent molecules claimed.

Accordingly, it was held in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

Appellants have not chosen to claim the DNA [product] by what it is but, rather by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the court of customs and Patent Appeals in *In re Hyatt*, 708F.2d 712. 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell of DNA or plasmid, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly, the disclosure is not commensurate in scope with the claims."

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7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
January 9, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600